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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,655	03/14/2005	Edwin Odell Miner	0M02-01	2401
36491 7590 04/04/2007 KUNZLER & ASSOCIATES 8 EAST BROADWAY			EXAMINER	
			SHEIKH, HUMERA N	
SUITE 600 SALT LAKE C	CITY, UT 84111		ART UNIT	PAPER NUMBER
	,		1615	*
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVER	Y MODE
3 MONTHS		04/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)
	10/527,655	MINER ET AL.
Office Action Summary	Examiner	Art Unit
	Humera N. Sheikh	1615
The MAILING DATE of this communication ap	opears on the cover sheet w	vith the correspondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPI WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUN .136(a). In no event, however, may a d will apply and will expire SIX (6) MO tte, cause the application to become A	ICATION. I reply be timely filed INTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133).
Status	•	
1) Responsive to communication(s) filed on 03.	January 2006.	
	is action is non-final.	
3) Since this application is in condition for allowed	ance except for formal mat	tters, prosecution as to the merits is
closed in accordance with the practice under	Ex parte Quayle, 1935 C.I	D. 11, 453 O.G. 213.
Disposition of Claims		
4) Claim(s) 1-20 is/are pending in the application	n.	
4a) Of the above claim(s) is/are withdra		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-20</u> is/are rejected.		
7) Claim(s) is/are objected to.	·	
8) Claim(s) are subject to restriction and/	or election requirement.	
Application Papers		
9) The specification is objected to by the Examin	er .	
10) The drawing(s) filed on is/are: a) ac		by the Examiner.
Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the correct		• •
11)☐ The oath or declaration is objected to by the E		
Priority under 35 U.S.C. § 119		•
12) Acknowledgment is made of a claim for foreign	n priority under 35 H S C	8 119(a)-(d) or (f)
a) ☐ All b) ☐ Some * c) ☐ None of:	in priority under 55 0.5.0.	g 113(a)-(a) or (i).
1.☐ Certified copies of the priority documen	nts have been received.	
2. Certified copies of the priority documen		Application No.
3. Copies of the certified copies of the price		
application from the International Burea		· ·
* See the attached detailed Office action for a lis	t of the certified copies not	t received.
,		
Attachment(s)		
) Notice of References Cited (PTO-892)	4) Interview	Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No	(s)/Mail Date Informal Patent Application
Information Disclosure Statement(s) (PTO/SB/08)	ווס שטווטאון וונכ	momai Fatent Application

DETAILED ACTION

Status of the Application

Receipt of the Information Disclosure Statement (IDS) filed 01/03/06 is acknowledged.

Claims 1-20 are pending in this action. Claims 1-20 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the

claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c)

and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

subject matter which the applicant regards as his invention.

Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

Claims 4 and 12 recite the limitation "<u>a.k.a. propylene glycol</u>". The claims are indefinite because it is unclear whether the limitation is merely exemplary in nature or whether it is actually intended to be part of the claim. It is suggested that the limitation "a.k.a. propylene glycol" be either deleted or positively recited.

* * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (U.S. Pat. No. 4,184,974) in view of Dodd *et al.* (U.S. Pat. No. 6,344,218).

The instant invention is drawn to a liquid antiseptic comprising: water; silver ion; polypectate and ethylenediaminetetraacetic acid (EDTA). The instant invention is also drawn to a method of preparing a liquid antiseptic, comprising the steps of: combining water, silver ion

and aqueous ammonia to form a silver ammonium complex solution; combining ethylenediaminetetraacetic acid (EDTA), sodium polypectate, glycerine and water to form a chelating solution; and combining the silver ammonium complex solution with the chelating solution to form a chelated silver solution.

Van Leuven ('974) teaches a liquid biocidal and cleanser composition comprising lauryl diethanolamide (2.7-6.5% by wt.), propylene glycol (1.2-2.5% by wt.), glycerine (4-6% by wt.), sodium polypectate (100-400 parts/million (ppm)), silver ion (13-250 ppm), a detergent that is nondeleteriously reactive with sodium polypectate (3.6-8.5% by wt.) and a sufficient water soluble base such as ammonium hydroxide to maintain a pH in the range from about 7.2 to 8.8; the balance of the composition being primarily sterile distilled water (see reference column 2, lines 1-19) and Abstract.

The silver ion can be added to the composition as silver nitrate (col. 2, line 20). The detergent can be the reaction product of from about 2.5 to about 6% by wt. dodecyl benzene sulfonic acid or a water-soluble salt thereof and from about 1.1% to about 3% by wt. triethanolamine (col. 2, lines 21-24).

Van Leuven teaches that the composition can be used for a variety of purposes such as a cleaner, topical biocide agent or vaginal lubricant (col. 2, lines 1-6). The composition is also useful for preserving human corpses, for treating condyloma and Herpes virus, for preventing Staphylococcus infection and as a lubricant for the delivery of a child at birth (col. 2, lines 25-29).

According to Van Leuven, the invention overcomes the undersirable effects of silver compounds by forming a silver polypectate that is completely stable at the specified concentrations (col. 2, lines 32-44).

In addition to the silver ion, which is preferably added as silver nitrate in this composition, there is sodium polypectate, which has a strong chelating activity with the silver (col. 2, lines 45-62). Van Leuven teaches that the proportion of sodium polypectate in the composition is in the range of about 100 to about 400 ppm by wt. The lower concentration of 100 ppm by wt. of sodium polypectate is found sufficient to provide adequate chelating activity with the silver ion to maintain it as a stable composition and inhibit its oxidation or decomposition upon exposure to light. It is believed that the sodium polypectate serves to ionize the silver in the composition to yield silver ion, which has biocidal activity (col. 3, line 60 – col. 4, line 12).

The composition also contains from about 3.6 to about 8.5% by wt. of a water-soluble detergent that is nondeleteriously reactive with sodium polypectate. This range meets Applicant's claimed range of surfactant of about 4.0-8.75%. Suitable examples of such a detergent is a linear alkyl sulphonate having from about 10 to about 12 carbon atoms in the alkyl chain. Such a sulphonate can be provided in the biocidal composition by using dodecyl benzene sulfonic acid or a water-soluble salt thereof in the range of from about 2.5 to about 6% by wt. of the composition and triethanolamine, in the range of from about 1.1% to about 3& by wt. of the composition (col. 4, lines 45-61). Commercially available dodecyl benzene sulfonic acid or its water-soluble salt can have minor variations in chain length and a few isomers of the dodecyl chain may also be present. Such material is widely used as surface-active agents common in

detergent compositions. These materials offer good cleaning action, lubricity and appropriate viscosity without adverse effects (col. 4, line 63 – col. 5, line 2). For higher viscosity and cleansing action, detergent materials such as sodium lauryl sulfate can also be used (col. 5, lines 14-44).

The composition also includes propylene glycol in the range of from about 1.2 to 2.5%. This material also has some bacteriocidal activity which cooperates with that of the silver to enhance the biocidal activity of the composition (col. 5, lines 45-55).

The composition also includes glycerine in the range of from about 4 to 8% (col. 5, lines 56-57) and about 4 to about 10% (see claim 1). This range meets Applicant's claimed glycerine range of about 5.5-11.5%.

The liquid biocidal composition also includes a small amount of pH adjuster such as a water-soluble base to maintain the pH in the range of from about 7.2 to 7.8 (col. 6, lines 6-8). This range is important for maintaining the stability of the composition over a prolonged period of time, for effective biocidal action and is also preferred for repeated application of the composition to the skin. Ammonium hydroxide is found to be quite compatible for use with the combination of sodium polypectate and silver nitrate (col. 6, lines 9-22).

The Examples at columns 6-14 demonstrate methods for the preparation of various compositions, such as cleansing agents. Example 1, for instance, shows the preparation of a topical cleansing agent according to the invention. A solution "A" comprising a silver ammonium complex was prepared by combining silver nitrate, distilled water and concentrated aqueous ammonia. The components were mixed together. A solution "B" was prepared by mixing glycerine, sodium polypectate and fresh distilled water. A solution "C" was prepared by

dissolving FDA #1 and #5 in distilled water. The topical cleansing agent was then prepared in a silver-lined reactor, to which distilled water and aqueous ammonia were added, to bring the water to a pH of at least 7.2. Carsofoam (containing triethanolamine, dodecylbennzene sulfuric acid, propylene glycol, lauryl diethanolamide and soft water) was then mixed into the contents of the reactor and stirred. The topical cleansing agent was packaged to avoid degradation of the silver due to sunlight.

With regards to the ranges claimed by Applicant, such as the ranges/amounts of 1,2propanediol, sodium polypectate, water and silver ion, Van Leuven does not explicitly teach the precise ranges, but does appear to teach similar and/or overlapping amounts of each component. Moreover, no unexpected results have been observed, which accrue from the instantly claimed ranges and/or amounts, since the prior art vividly teaches a liquid biocidal cleansing composition comprising the same components, employed in effective amounts to yield a suitable biocidal composition. It would have been deemed obvious to one of ordinary skill in the art to determine suitable/effective ranges and/or amounts through routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art. Furthermore, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, the prior art expressly teaches a liquid biocidal composition comprising

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suitable amounts of each particular component (i.e., water, polypectate, silver ion, glycerine,

surfactant & propylene glycol) to result in a stabilized and effective cleansing composition.

Van Leuven teaches chelation activity between sodium polypectate and silver ion to

maintain stability and inhibit oxidation or decomposition of the composition (col. 3, line 60 -

col. 4, line 35). Van Leuven does not teach ethylenediaminetetraacetic acid (EDTA).

Dodd et al. ('218) teach stable aqueous skin deodorizing and sanitizing compositions that

comprise chelators, such as ethylenediaminetetraacetic acid (EDTA) and other aminocarboxylate

chelators, salts and mixtures thereof (see col. 20, lines 1-18). Dodd et al. teach that chelators,

such as EDTA can increase preservative effectiveness against Gram-negative bacteria, especially

Pseudomonas species (col. 20, lines 12-18).

It would have been obvious to one of ordinary skill in the art at the time the invention

was made to incorporate the chelating agent, EDTA, as taught by Dodd et al. within the liquid

biocidal compositions of Van Leuven. One of ordinary skill in the art would be motivated to do

so with a reasonable expectation of success because Dodd et al. teach stable skin deodorizing

and sanitizing compositions that comprise chelators such as EDTA and explicitly teach that

EDTA is an effective chelating agent useful for its' preservative properties, especially against

Gram-negative bacteria. The expected result would be a stabilized, highly effective liquid

antiseptic formulation that exhibits enhanced biocidal properties and effects.

Conclusion

-- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for

the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

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PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH PRIMARY EXAMINER

Art Unit 1615

March 30, 2007

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